JAN - 8 2004

Assigned 510(k) number: K033643

Bayer Healthcare

CO_2 Calibrator/Diluent

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	Kenneth T. Edds Ph.D.
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Phone:	(914) 524-2446
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e-mail:	ken.edds.b.@bayer.com

Date Summary Prepared:	November 17, 2003

2. Device Information

Proprietary Name:	CO_2 Calibrator/Diluent
Common Name:	Calibrator
Classification Name:	Calibrator
Class:	Class II
CFR:	862.1150
Product Code:	75 JIT

3. Predicate Device Information

Name:	Calibrator for automated systems
Manufacturer:	Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250
510(k) Number:	K990460

4. Device Description

The CO_2 Calibrator/Diluent is an aqueous liquid solution containing bicarbonate at a defined concentration.

5. Statement of Intended Use

The CO_2 Calibrator/Diluent is intended for *in vitro* diagnostic use to calibrate the enzymatic determination of CO_2 on various Bayer diagnostic instruments. To calibrate Technicon RA, opeRA, and ADVIA IMS systems, this product is used in conjunction with Bayer Chemistry Calibrator (Prod. No. T03-1291-62). To calibrate ADVIA Chemistry systems, this product is used as a stand-alone product.

6. Product Performance

The stability of the CO_2 Calibrator/Diluent value has been validated according to Bayer procedures and is based on the results of three separate lots of calibrator material. The performance of the calibrator is similar to other products in commercial distribution intended for similar use.

7. Product Characteristics

Characteristic	CO_2 Calibrator/Diluent	Roche Calibrator for Automatic System
Intended use	The CO_2 Calibrator/Diluent is intended for *in vitro* diagnostic use to calibrate the enzymatic determination of CO_2 on various Bayer diagnostic instruments. To calibrate Technicon RA, opeRA, and ADVIA IMS systems, this product is used in conjunction with Bayer Chemistry Calibrator (Prod. No. T03-1291-62). To calibrate ADVIA Chemistry systems, this product is used as a stand-alone product.	For use as a calibrator of clinical chemistry assays for automated analytical procedures.
Format	Liquid – aqueous solution	Lyophilized pooled human serum with constituents added as required to obtain desired component levels.
Stability	• Stable at 2-8 °C until last day of the month (expiration date) printed on label. • Stable for thirty (30) days when properly capped once the diluent vial is opened and stored at 2-8°C.	• Stable at 2-8°C until expiration date. • Stable 2 days when reconstituted, stoppered, protected from light and stored at 2-8°C, with exception noted in labeling.
Level	Single level	Single level

Constituent Analytes

Bayer SETpoint CO2 calibrator/Diluent	Roche Calibrator for Automated Systems
Bicarbonate	*Bicarbonate*
	ALBUMIN
	BILIRUBIN, DIRECT
	BILIRUBIN, TOTAL
	CALCIUM
	CHOLESTEROL
	CREATININE
	GLUCOSE
	IRON
	MAGNESIUM
	PHOSPHORUS, INORGANIC
	TOTAL PROTEIN
	TRIGLYCERIDES
	UREA NITROGEN
	URIC ACID
	SODIUM
	POTASSIUM
	CHLORIDE
	LACTATE
	PHOSPHOLIPIDS
	SALICYLATE
	UNSATURATED IRON-BINDING CAPACITY
	ACID PHOSPHATASE
	ALKALINE PHOSPHATASE
	ALANINE AMINOTRANSFERASE
	CHOLINESTERASE
	CREATINE KINASE
	GAMMA-GLUTAMYLTRANSFERase
	GLUTAMATE DEHYDROGENASE
	ALPHA-HYDROXYBUTRATE DEHYDROGENASE
	LACTATE DEHYDROGENASE
	LIPASE
	UIBC
	LDL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 8 2004

Kenneth T. Edds, Ph.D.
Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k033643
Trade/Device Name: Calibrator/diluent for CO_2
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 19, 2003
Received: November 20, 2003

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033643

Device Name: Calibrator/diluent for CO_2

Indications for Use:

The CO_2 Calibrator/Diluent is intended for *in vitro* diagnostic use to calibrate the enzymatic determination of CO_2 on various Bayer diagnostic instruments. To calibrate Technicon RA, opeRA, and ADVIA IMS systems, this product is used in conjunction with Bayer Chemistry Calibrator (Prod. No. T03-1291-62). To calibrate ADVIA Chemistry systems, this product is used as a stand-alone product.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033643